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| 22850 7590 02/18/2011 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET | | | EXAMINER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| | Application No. | Applicant(s) | | |
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| | 10/564,368 | YAMAGISHI ET AL. | | |
| Office Action Summary | Examiner | Art Unit | | |
| | DARRYL C. SUTTON | 1612 | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION (6(a). In no event, however, may a reply be tirrill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. sely filed the mailing date of this communication. (35 U.S.C. § 133). | | |
| Status | | | | |
| 1) ☐ Responsive to communication(s) filed on 18 Oc 2a) ☐ This action is FINAL. 2b) ☐ This 3) ☐ Since this application is in condition for allowant closed in accordance with the practice under E | action is non-final. ace except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) ☐ Claim(s) 2.3.5 and 7-33 is/are pending in the all 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 2.3.5 and 7-33 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | vn from consideration. | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/29/2010. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | |

This 2nd Non-final Office Action is in response to the amendment filed 10/18/2010. New claims 30-33 have been added.

Applicant's arguments filed 10/18/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 5 and 7-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 recite the limitations "said calcium salt of organic acid" and "the calcium salt of organic acid" in lines 13 and line 8 of the claims respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 5, 7, 9, 12, 13, 26-29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ubsen et al. (US 5,605,675) in view of Tomlinson et al. (4,048,300) and Gates et al. (US5,882,630).

Ubsen et al. teach applying to the teeth a composition in two phases which do not react with one another until introduced into the oral cavity to remineralize teeth without demineralization of dental enamel (Abstract and column 2, line 66 - column 3, line 3, column 3, liens 55-58 and line 66 - column 4, line 3 and column 9, lines 6-7). One phase of the composition, such as a paste, gel or solution, contains at least one water-soluble calcium salt and the other phase, i.e. paste, gel or solution, contains at least one water-soluble inorganic phosphate salt and at least one water-soluble fluoride salt, i.e. more than one fluorine source in the composition and at least one in the phase with the phosphate; in this way the ions which effect remineralization can be absorbed by the dental enamel and their subsequent reaction causes rehardening of demineralized areas in the dental enamel (column 3, lines 3-9, line 60 and line 64, column 8, lines 49-57 and column 4, lines 11-13), i.e. the calcium, phosphate and

fluorine ions react to form calcium phosphate precipitate. Due to the presence of the fluoride ion, the remineralized enamel is more resistant to demineralization than was the original enamel (column 4, lines 20-22). Each solution should have a pH of from about 4.5 to 10 before and after the precipitation reaction (column 4, lines 43-46). Suitable water-soluble calcium salts include calcium glycerophosphate (column 5, lines 10-12). Suitable water-soluble inorganic phosphates include alkali and ammonium salts of orthophosphoric acid (column 5, lines 21-26). Suitable fluoride compounds include sodium fluoride and sodium monofluorophosphate; if monofluorophosphate salts are used as the fluoride source, they could be present in the first component along with the calcium cations without departing from the present invention (column 5, lines 41-42 and lines 51-59). The essence of the present invention lies in the mixing of components and the quick and timely application of the resulting solution which will precipitate calcium phosphate, calcium fluoride, and calcium fluoro-apatite in subsurface enamel of teeth. Before such precipitation occurs, the mixture comprising the solution must be quickly applied to the teeth (column 9, lines 33-40).

Ubsen et al. do not teach the method of alternately applying the separate compositions; the molar ratios or amounts of compounds as in instant claims 6 and 26-29; or the pH of each phase.

Tomlinson et al. teach dental preparations, such as toothpastes, tooth powders, gels and mouth washes, having calcium and phosphate components (Abstract, column 10, lines 28-30, column 18, lines 40-41). The novel compounds of the invention can be used in oral preparations and provide a long-term source of components for the

remineralization of dental enamel (column 6, lines 52-58). Tomlinson teaches a composition with a first component comprised of fluoride and orthophosphoric acid with a pH of about 3 to 4; and a second component comprised of comprised of a calcium salt having a pH of about 7 (column 9, lines 28-39). Tomlinson teaches a method of alternately applying the compositions to the teeth. The teeth are subjected to fluctuating pH in the presence of fluoride, orthophosphate, and calcium ions which not only serves to prevent loss of calcium and orthophosphate ions from dental enamel, but also facilitates growth and development of the apatite crystals so that some remineralization of pits and fissures in the tooth enamel occurs. Optimum incorporation of fluoride ions into the apatite crystals structure occurs as the pH range rises from about 4 to about 7 (column 8, lines 47-68, column 17, Example 12). Apatite material containing fluoride containing materials serves to provide anti-caries protection and remineralization (column 10, lines 39-44). When orthophosphoric acid is used, an additional source of calcium ions is required such as from calcium carbonate (column 5, lines 24-27).

Tomlinson does not teach the embodiment comprised of the specific two components of the composition; or the molar ratios or amounts of compounds as claimed in claims 2, 3, 5, 7, 9, 12, 13, 26-29, 31 and 33.

Gates et al. teach that calcium glycerophosphate enhances the activity of ionic monofluorophosphates, such as sodium monofluorophosphate in oral compositions (column 3, lines 10-28).

Gates et al. do not teach a method of treating teeth comprising alternately applying a first and second composition to a tooth.

At the time of the invention, it would have been obvious to use calcium glycerophosphate as the calcium source in the second composition and to include the monofluorophosphate salt in the second component since Ubsen et al. teaches calcium glycerophosphate and the incorporation of monofluorophosphate salt in the composition with the calcium source and that the composition is comprised of at least one fluoride salt; and since Gates et al. teaches that calcium glycerophosphate enhances the activity of monofluorophosphates. It would have also been obvious to incorporate an inorganic fluoride salt, i.e. sodium fluoride, in the first component, since Ubsen et al. teaches at least one fluoride source and that it should be in the component with the phosphate source. Further, incorporation of both fluoride sources would provide additional fluoride ions for diffusion through the dental enamel and incorporation into the calcium phosphate precipitate, helping to create remineralized dental enamel that is resistant to demineralization as taught by Ubsen et al.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Ubsen et al. to the method of alternately applying the separate compositions to teeth at the specific pHs of Tomlinson et al. motivated by the desire to facilitate the remineralization and anti-caries protection of pits and fissures in tooth enamel by simultaneously producing the optimum incorporation of fluoride ions as taught by Tomlinson et al. Further, it would negate the necessity to quickly mix and

apply the composition as taught by Ubsen et al., thereby facilitating the dissolution and precipitation inside of the dentin of teeth.

In regards to claims 9, 26-29, 31 and 33, the prior art does not teach the specific concentrations or molar ratios of the compounds. However, the invention suggested by combining Ubsen et al. and Tomlinson et al. is comprised of from about 0.05% to 15% of a phosphate salt, from about 0.05% to 15% of a calcium salt and fluoride salt from about 0.01 to about 5%, other ingredients of the composition are optional, i.e. "may" be used, therefore, optimization of remineralization and optimization of the incorporation of fluoride in apatite crystals is obtained through routine experimentation by varying the amounts of the phosphate salt, fluoride salt, and calcium salt in the respective aqueous solvents or carriers and optionally adding and varying the amounts of other ingredients; and would result in the concentrations and molar ratios of the instant claims.

Claims 14-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ubsen et al., Tomlinson et al. and Gates et al. as applied to claims 2, 3, 5, 7, 9, 12, 13, 26-29, 31 and 33 above, and further in view of Grabenstetter et al. (U.S. 4,083,955).

Ubsen et al., Tomlinson et al. and Gates et al. are discussed *supra*.

Ubsen et al., Tomlinson et al. and Gates et al. does not teach the times ranges for application of each component is from 5 to 30 seconds.

Grabenstetter et al. teach two compositions comprised of a cation, i.e. calcium, and an anion, i.e. phosphate which are sequentially applied to dental enamel resulting in mineralization of dental enamel (Abstract). The sequential application consists of two

steps which may be performed in any order (column 2, lines 13-20). While the length of contact is not critical, it is necessary for the length of time to be great enough to allow diffusion of the ions through the tooth's surface (column 2, lines 51-56). The components can be sequentially delivered to the surface of the tooth by means of two separate delivery vehicles, each containing one component. The ionic ingredients can be topically applied by means of tape or other adhesive material (column 5, lines 23-27). Examples of two vehicle systems are mouthwash-mouthwash, toothpaste-toothpaste, toothpaste-mouthwash; and so forth.

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Grabenstetter et al. do not teach the composition of claim 9.

In regards to claims 14-17, where the general conditions of a claim are disclosed in the prior art, it is not inventive to determine the optimum or workable ranges through routine experimentation. Since, Grabenstetter et al. teach that the length of time of application must be sufficient to allow diffusion of ions through the tooth's surface, the remineralization of teeth is optimized through routine experimentation by varying the amount of time each component is applied to the teeth; and by varying the amount of repetitions of the method.

In regards to claim 21, it would have been obvious to modify the delivery vehicle of each component since it is well known in the art that combinations of different delivery vehicles has been used to facilitate tooth remineralization as taught by Grabenstetter et al.

Claims 8, 10, 11, 18-20, 22-25, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ubsen et al., Tomlinson et al., Gates et al. and Grabenstetter et al. as applied to claims 14-17 and 21 above, and further in view of Wiesel (U.S. Patent 6,287,120).

Ubsen et al., Tomlinson et al., Gates et al. and Grabenstetter et al. are discussed *supra*.

Ubsen et al., Tomlinson et al., Gates et al. and Grabenstetter et al. do not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

Wiesel teaches an embodiment of a carrier coated with a paste, gel or solution which contains medicaments which promote the repair or remineralization of tooth enamel (Abstract, column 8, lines 28-36). Wiesel teaches that the carrier is a non-woven, porous material which is first dipped in one solution and that additional solution may be applied to the porous material while it remains on the patient's teeth (column 3, lines 65-67, column 4, lines 1-5).

Wiesel does not teach a composition comprised of two components.

At the time of the invention it would have been obvious to modify the product and method suggested by combining Ubsen et al., Tomlinson et al., Gates et al. and Grabenstetter et al. to include the carrier of Wiesel since the method of applying compositions for remineralization of teeth with a carrier was known in the art.

In regards to claim 11, it would have been obvious to impregnate the carrier with water immediately prior to application to a tooth motivated by the desire to mix either

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composition with water to produce either phosphate or calcium ions immediately before applying the device to teeth.

In regards to claim 20, at the time of the invention it would have been obvious to modify the product suggested by combining Ubsen et al., Tomlinson et al., Gates et al., Grabenstetter et al. and Wiesel to be comprised of a mouthwash and dentifrice since the components for remineralizing teeth can be applied in different delivery vehicles as taught by Grabenstetter et al.

In regards to claims 22-25, the prior art does not teach the specific concentrations or molar ratios of the compounds. However, the invention suggested by combining Ubsen et al., Tomlinson et al., Grabenstetter et al. and Weisel et al. is comprised of from about 0.05% to 15% of a phosphate salt, from about 0.05% to 15% of a calcium salt and fluoride salt from about 0.01 to about 5%, other ingredients of the composition are optional, i.e. "may" be used, therefore, optimization of remineralization and optimization of incorporation of fluoride in apatite crystals is obtained through routine experimentation by varying the amounts of the phosphate salt, fluoride salt, and calcium salt in the respective aqueous solvents or carriers and optionally including and varying the amounts of other ingredients and would result in the concentrations and molar ratios of the instant claims.

Applicant's Arguments

Applicants argue that the claimed invention is distinct from the cited art in that the art does not disclose alternately applying separate compositions or compositions meeting the requirements of (A) and (B) which are maintained discretely. Ubsen et al. fail to disclose alternately applying the separate compositions and also fail to disclose the pH of the separate compositions or the molar ratios. Tomlinson et al. discloses alternate application, but merely discloses monofluorophosphates and is silent about calcium salts of polyol phosphate. Accordingly, the skilled artisan would not expect the claimed compositions (A) and (B) as claimed or alternately applying thereof to thereby maximum fluoride uptake.

The Examiner disagrees.

Since the rejection is a 103 obviousness rejection, no one piece of prior art is required to teach each and every limitation of the claims. As discussed supra, the primary reference Ubsen et al. provides a starting point for the rejection by citing a two component composition. One phase/component is comprised of from about 0.05% to 15% of at least one water-soluble inorganic phosphate salt and from about 0.01 to about 5% of at least one water-soluble fluoride salt to provide fluoride ions for remineralization of enamel that is more resistant to demineralization than was the original enamel, including sodium fluoride, while the other is comprised of from about 0.05% to 15% of at least one water-soluble calcium salt and possibly an alkali monofluorophosphate to provide fluoride ions for remineralization of enamel that is more resistant to demineralization than was the original enamel; and that each solution should have a pH of from about 4.5 to 10. A prior art reference is evaluated for all that it

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reasonably suggests, and is not limited to preferred embodiments or working examples. Accordingly, Ubsen et al. teaches the two components of the compositions as claimed but as Applicant points out, does not teach alternate application. However, as discussed *supra*, Tomlinson et al. teaches a composition comprised of a first component comprised of fluoride and orthophosphoric acid with a pH of about 3 to 4; and a second component comprised of comprised of a calcium salt having a pH of about 7; and the benefits of alternately applying the compositions, including that optimum incorporation of fluoride ions into the apatite crystals structure occurs as the pH range rises from about 4 to about 7. The skilled artisan would reasonably expect a correlation between alternating pH and optimum fluoride uptake, and would therefore reasonably expect to provide remineralization of teeth and that optimum incorporation of fluoride would be provided by the components of the compositions of Ubsen et al. if the pH of the first component was adjusted to about 3 to 4 and the second was adjusted to about 7, and if the components were alternately applied according to the method of Tomlinson et al. Furthermore, Gates et al. teaches that calcium glycerophosphate, which is disclosed by Ubsen et al. as a calcium ion source is used in conjunction with sodium monofluorophosphate, which is also disclosed by Ubsen et al., the activity of monofluorophosphate is enhanced. Ubsen et al. teaches that a monofluorophosphate compound is incorporated with the calcium source. Therefore, enhancement of fluoride uptake is expected from the method suggested by combining Ubsen et al., Tomlinson et al. and Gates et al. due to the fluctuation of pH as taught by Tomlinson et al. and due to

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the enhancement of the monofluorophosphate activity by combining with the calcium glycerophosphate as taught by Gates et al.

Applicant argues that Table 4 of the Declaration filed 01/25/2010, provides proof of the allegation of unexpected results. Table 4, applicant alleges, provides clear evidence of the importance of a second composition containing monofluorophosphate and a calcium salt of a polyol phosphate wherein an aqueous solution has a pH value ranging form 6 to 12. In paragraph 17, it is clearly summarized that a mixed solution having a low pH in due to the presence of calcium nitrate or calcium lactate would not be suitable for repairing teeth.

The results in the Table do not, however, appear to be "unexpected". As discussed *supra*, the incorporation of a combination of calcium glycerophosphate and sodium monofluorophosphate would reasonably be expected to enhance fluoride activity, including incorporation into remineralized enamel and fluoride uptake when the components suggested by combining Ubsen et al., Tomlinson et al. and Gates et al. are alternately applied and the pH is fluctuated.

Applicant argues that the Examiner has compared to comparative examples rather than comparing the comparative examples to the example of the present application. A fluoride uptake of 250% higher was obtained using the alternate application is in no way expected in view of the disclosure of Ubsen et al., Tomlinson et al., Grabstetter et al. and Wiesel. In respect to the 10% increase, in premixed treatment, because MFP accelerates formation of crystal of calcium phosphate and

calcium fluoride, fluoride uptake is increased. This represents yet another distinction from the art as the compositions of Ubsen et al. are premised on pre-mixing, no one in the art would think to add MFP into the compositions of Ubsen et al. Applicant argues that the Experimental data presented in the Declaration submitted herewith, dated 10/18/2010, clearly illustrates the substantial benefits flowing from the claimed method, which are enough to rebut a *prima facie* case of obviousness. Applicant points to Table 3 and 4 of the Declaration filed 01/25/2010 and Paragraphs 18 and 19 of the present Declaration, dated 10/18/2010, for evidence of the alleged unexpected results.

The Examiner disagrees.

As discussed in the Non-final office action dated 05/17/2010, comparative example B2 discloses approximately a 10% increase in fluoride uptake as a result of inclusion of 1.89% of monofluorophosphate in part A. Accordingly, the skilled artisan would reasonably see the benefit of using both a monofluorophosphate salt in part A and sodium fluoride in part B based on this increase; and based on the teachings of Gates et al. would reasonably expect that incorporation of calcium glycerophosphate as the calcium source would further enhance fluoride uptake. Ubsen et al. clearly teach monofluorophosphate salts as a fluoride ion source and that if monofluorophosphate salts are used as the fluoride source, they could be present in the first component along with the calcium cations without departing from the present invention. Combined with the teaching of Tomlinson that alternating the components and thereby alternating the pH provides for optimum incorporation of fluoride ions into the apatite crystals, i.e.

fluoride uptake, the skilled artisan would reasonably expect further enhanced fluoride uptake when the components are alternately applied.

Furthermore, assuming *arguendo*, that unexpected results have been shown, the claims would still not be commensurate in scope with those showings.

Table 3 demonstrates that a composition comprised of component (A) comprising 0.55% sodium fluoride as a inorganic fluoride source, 4.0% potassium phosphate as an inorganic phosphoric acid salt source, with a pH value ranging of 4.07 and molar ratio of inorganic fluoride to inorganic phosphoric acid salt of approximately 0.5; and component (B) comprised of 1.89% monofluorophosphate and 3.42% calcium glycerophosphate as a calcium salt of polyol phosphate with a pH of 8.12; the ratio of sodium fluoride of (A) to calcium glycerophosphate of (B) of approximately 0.5. The claims are, however, broader. For instance, the claims recite inorganic fluoride and inorganic phosphate broadly, but the showing is limited to sodium fluoride and potassium phosphate. It is not clear that the results of the showings can be extrapolated to inorganic fluoride sources and inorganic phosphates in general, since each would dissociate differently and therefore would produce fluoride and phosphate ions at different rates. Similarly, the claims recite monofluorophosphate and calcium salt of a polyol phosphate broadly, but the showing is limited to monofluorophosphate and calcium glycerophosphate. It is not clear that the results obtained with the monofluorophosphate and calcium glycerophosphate can be extrapolated to monofluorophosphates in general since all monofluorophosphates do not supply fluoride directly; and to calcium salts of polyol phosphates in general since the salts would also

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dissociate at different rates and provide phosphate ions at different rates. Further, polyol phosphates would affect the pH of the solution differently. The claims recite a ratio of inorganic fluoride to inorganic phosphoric acid or salt thereof in the ranges of 0.1 to 10 and 0.1 to 3 but the showing is limited to a ratio of approximately 0.5. It is not clear that the results of the showing can be extrapolated to the recited range, since the invention is dependent on a mixture of fluoride, calcium and phosphate ions being available to the tooth enamel. Varying the amount of fluoride, i.e. by using ratios smaller than 0.5, would reduce the amount of fluoride available which would reduce fluoride uptake. Similarly, the claims recite a ratio of inorganic fluoride to calcium salt of polyol phosphate from 0.2 to 5 but the showing is limited to a ratio of approximately 0.5. It is not clear that the results of the showing can be extrapolated to the recited range, since the invention is dependent on a mixture of fluoride, calcium and phosphate ions being available to the tooth enamel. Varying the amount of fluoride, i.e. by using ratios, smaller than 0.5, would reduce the amount of fluoride available which would reduce fluoride uptake.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/ Examiner, Art Unit 1612

/Frederick Krass/ Supervisory Patent Examiner, Art Unit 1612

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